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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 020.0336.US.CON 8613 10/645,980 08/22/2003 Gust H. Bardy EXAMINER 22895 7590 10/19/2004 PATRICK J S INOUYE P S LAYNO, CARL HERNANDZ 810 3RD AVENUE PAPER NUMBER ART UNIT **SUITE 258** SEATTLE, WA 98104 3762

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		11X	
Office Action Summary	Application No.	Applicant(s)	
	10/645,980	BARDY, GUST H.	
	Examiner Carl H. Layno 10/16/2004	Art Unit	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address			
Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on 22 August 2003.			
· <u> </u>			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
 4) Claim(s) 1-59 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 21-30,32-41 and 43-50 is/are allowed. 6) Claim(s) 1-11,20,31,42 and 51-59 is/are rejected. 7) Claim(s) 12-19 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 			
Application Papers			
9)☐ The specification is objected to by the Examiner.			
10)⊠ The drawing(s) filed on <u>22 August 2003</u> is/are: a)⊠ accepted or b) \square objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
Attachment(s)			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/C Paper No(s)/Mail Date <u>various</u> .	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other:		

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Application Serial No. 09/789,416, filed February 20, 2001, which is a Continuation of U.S. Patent No. 6,221,011, filed July 26, 1999.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on August 22, 2003, September 26, 2003, December 15, 2003, March 18, 2004, April 30, 2004, and August 2, 2004.

Drawings

3. Applicant's formal drawings, which were filed on August 22, 2003, have been approved by the Examiner.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 31, 42, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 31, lines 3-4 include a reference to the term "the patient status indicator". As written, this term has no antecedent basis in this claim or base claim 29. To overcome this rejection, the Examiner suggests changing the dependency of the claim to depend from claim 30, which defines this term.

In regard to claim 42, line 2 includes a reference to the term "the patient status indicator". As written, this term has no antecedent basis in this claim or base claim 40. To overcome this rejection, the Examiner suggests changing the dependency of the claim to depend from claim 41, which defines this term.

In regard to claim 53, lines 2-3 include a reference to the term "the patient status indicator". As written, this term has no antecedent basis in this claim or base claim 51. To overcome this rejection, the Examiner suggests changing the dependency of the claim to depend from claim 52, which defines this term.

Double Patenting

6. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,221,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same basic structures of a database/"database server", a server/"network server", a medical device adapted to be implanted, and an analysis module/"application server" are present in each claim as are their corresponding functions.

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7. Claims 51-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-31 of U.S. Patent No. 6,277,072.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims disclose computer-readable storage media for code performing the same claimed functions. Only syntax differences exist between the claims, namely, the applicant's use of the words "code for" preceding each code functions present on the media.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 10, 11, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Snell '705.

The Snell '705 patent describes a distributed system (Fig. 1) for processing and storing medical data from implantable devices including applicant's claimed elements of a database 103, a network server 102, which performs the function of applicant's analysis module, an implantable medical device(s) 105, and network programmer(s) 104, which perform the duties of applicant's "server". Applicant's attention is directed to col.9. In use the network programmer 104 obtains measured data from a pacemaker (i.e. the implanted device) and sends it to the network server 102 (see Table I - col.9, lines 57-62). The network server analyzes received data to make recommendations regarding baseline pacer settings (Table I - col.9, lines 31-42) and creating a report to a physician detailing patient status (Table I - col.10, lines 13-19).

In regard to claim 10, the implantable devices of the Snell system monitor a patient's electrocardiograms (ECGs), which are then processed by the system (col.3, lines 56-60); therefore, the "reference measures" constitute, in some part, ventricular electrical activity.

Allowable Subject Matter

- 10. Claims 31, 42, and 53 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- Claims 2-9 and 12-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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12. Claims 21-30, 32-41, and 43-50 are allowed.

13. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 21 recites a computer readable storage medium comprising code which regularly records and stores "measures sets" of data from a medical device adapted to be implanted. It is unclear from the references of the prior art in which information from implantable medical devices is stored in databases (i.e. Snell '705, Krichen et al '309, etc.) whether or not data is read from these implanted devices on a regular basis and if so, whether or not computer storage media are used to store the software responsible for performing this task. Consequently, the Examiner deems claim 21 and its depending claims to be allowable. For these reasons, independent claims 29 and 40 and their depending claims, which disclose corresponding system and method claims, are also deemed to be allowable.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All FAXed correspondence should be sent to the Office's Official FAX number (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

CARL LAYNO
PRIMARY EXAMINER

Carl H. Layro

CHL

10/16/2004